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Supplemental Submission in Response to published

"Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals"

Docket No. 00D-0053
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061, (HFA-305)
Rockville, MD 20852

To the Food and Drug Administration:

I have already submitted my comments regarding this issue once. However, having just come back from the AORN 2000 conference held in New Orleans this first week in April, I learned from numerous "reprocessors" what it was they were doing in the marketplace as of this date. What I learned concerns me greatly and gives an urgency to the need for the Food and Drug Administration to take immediate legal and legitimate action.

I have already stated my concerns that the current direction of FDA "thinking" on this matter is a legal "dead-end". Other than stating the obvious, that no amount of wishful thinking will change a service activity into a reprocessing activity, (as defined in the authorizing statutes), no further comments on the legal process will be forthcoming in this supplemental document.

What will be included in this document are a report on the comments I received from various officers, controlling persons, and representatives of "Third-Party Reprocessing" companies present at the AORN 2000 conference as well as my concern and response to those comments. There were actually many areas of concern, but three specific comments delineate the worst and most important areas for concern.

The first comment discussed is especially troubling. A senior official of a company very active in the "Association of Reprocessors of Single Use Devices" (ARSUD) met with me. This individual was instrumental in forming ARSUD and is a major policy maker in that organization. He stated:

"Ron, I know what's happening in the FDA. it's all over. Six months from now, everybody will have to file a 510(k) for every instrument they reprocess."

There are two primary possibilities in interpreting this comment, especially when factoring in who said it. First, if the gentleman knows what he is talking about, (1) ARSUD (made up of large companies which operate to the detriment of the smaller independent service companies) has used its influence with the FDA. (2) The "fix" is in and all the public comments requested by this Draft Guidance are so much "horse flatulence". (3) The position of the FDA regarding the issues in the

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Draft Guidance has already been determined, the chosen course of action has been selected, and certain influential parties have been informed in order to prepare. A number of statutes and regulations have been broken as a result.

The second possibility is almost equally disturbing for a different reason. If this executive of a major reprocessor really believes that the FDA has already selected a course of action (and this belief is erroneous) where did he get his information? Who within the FDA is giving out false and/or erroneous information? What is going on to solve public concerns when reputable individuals are so misinformed? What does this say about our ability to work together to resolve the problems facing our industry?

There is obviously a third possibility that the individual making the comment was untruthful. However, given the tenor of the conversation, the person involved, and the overall circumstances, this is a low-probability option. My belief is that the person was speaking from personal knowledge gleaned from conversations held directly with FDA staff. My belief is that it was his honest opinion as to where things stood within the FDA, and that this opinion was based on direct and personal information given to him.

The second Comment heard outlines the most serious problem facing the "single-use" service industry. A president of a reprocessing company stated directly to me:

"WE just finished our clinical evaluation of our cleaning protocols for disposable retractable trocars and we will start reprocessing them".

Three years ago, my company found ways to clean retractable trocars such that virtually no bioburden remained present. That was not the problem. The problem was with the inherent risk of the instrument itself. The FDA is fully aware that retractable trocars do not always retract when they are new. There is a failure rate, albeit a very small one, for a variety of reasons including improper use.

What is going to happen to all the positive things our industry has accomplished when an inept Doctor hits a major vessel or organ with a retractable trocar that has been "reprocessed"? What will happen when a Doctor, skilled in the procedure, utilizes a "reprocessed" retractable trocar that doesn't retract? These things do happen and unlike new instruments, any problems which may occur will be directly blamed on reprocessing rather than any inherent defect in either the instrument or the skill with which it is utilized.

It is grossly unfair for those of us who have made the ethical decision to refuse to service controversial instruments, to be tarred with the same brush as the unscrupulous companies when something serious does happen. As long as certain companies are prepared to reprocess high risk instruments, it will happen.

The third and last comment I report to you brings out the previous and most serious issue even more. Certain companies have decided to reprocess angioplasty balloon catheters and similar instruments. Regarding angioplasty balloon catheters, a representative of a reprocessing company said to me

"yeah... we've done \$... .. of dollars worth and so far, we haven't yet had a problem."

"...so far, we haven't yet..." is not even remotely good enough. The basic problem with these and other high risk instruments is not that they may not be serviced properly. It is entirely possible that such servicing can be verified with sufficient data to be safe and effective.

Nevertheless, the level of safety of many "high risk" instruments relies primarily upon the skill and diligence of the surgeon wielding it in a procedure. We have created a built-in excuse and protection for malpractice. The greed and stupidity of a certain segment of our industry may destroy us all. Between some time in the future when the FDA finalizes whatever it intends to require to prove efficacy and safety, and the "here and now", some patient is likely to be seriously injured or even killed in a procedure using a reprocessed instrument. That event will trigger such an adverse wave of publicity that everyone involved will suffer the consequences. Those consequences will be catastrophic.

The adverse publicity we are now receiving on unwarranted rumors and "fluff" media coverage is bad enough. What will happen to us when a face and a name is attached to a "victim" of reprocessing and paraded throughout the media?

The FDA must act now. It must publish a list of instruments for which it has received Medical Device Reports showing material serious harm occurring to a patient from misuse or failure, even when brand new. The FDA must advise healthcare providers that the FDA recommends the instruments on this list not be serviced or reprocessed at this time until final regulations or guidelines are determined. The FDA does not need to wait to exercise its regulatory "muscle" in order to protect the public. We need the list of proscribed instruments now, not later.

If the FDA does not make such recommendations, whatever happens in the interim period to harm us all will be as much the fault of the FDA as the actual unscrupulous company providing such reprocessing. The current lack of advice and direction from the FDA on this matter cannot be tolerated further; not with people talking about servicing retractable trocars, angioplasty balloon catheters, and other extremely high-risk medical devices which already have a history of failure.

If the FDA does not publish a recommended "proscribed" list and a patient is harmed or lost as a result of FDA inaction, at least these public comments will exist to show that the FDA was encouraged to do the right thing to protect the public welfare.

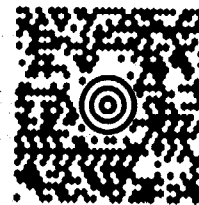
We are actually looking at two very diverse industries. The first industry is one in which instruments can be serviced and recovered at little or no risk to the public welfare. This industry can be regulated using recommendations and guidelines on low and moderate risk instruments stemming from GMP and ISO quality assurance standards. We belong to that industry. We voluntarily comply with the highest QA standards applicable. The other diverse industry is one that is ignoring common sense, reprocessing high-risk instruments that fail on occasion with first use, and allows the profit motive to overcome discretion and prudent judgment. In addition to separating these diverse activities, the FDA must take action to protect us all from the greed of high-risk "reprocessors".



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